What are the most common reasons for return of ethics submissions? An audit of an Australian health service ethics committee

Brandenburg, Caitlin; Thorning, Sarah; Ruthenberg, Carine

Published in:
Research Ethics

DOI:
10.1177/1747016121999935

Original Article; Empirical

Research Ethics
1–13

DOI: 10.1177/17470161211999935
journals.sagepub.com/home/rea
SAGE

What are the most common reasons for return of ethics submissions? An audit of an Australian health service ethics committee

Caitlin Brandenburg
Gold Coast Health, Australia
Bond University, Australia

Sarah Thorning
Carine Ruthenberg
Gold Coast Health, Australia

Abstract

One of the key criticisms of the ethical review process is the time taken to decision, and associated resource use. A key source of delay is that most submissions are required to respond to at least one request for further information or clarification from the Human Research Ethics Committee (HREC). This study audited the request letters of a single Australian public health HREC using content analysis. Twenty-four submissions were analysed, including 355 individual request elements. Most submissions received a single request letter. There was a mean number of 14.2 (SD = 5.5) elements per letter for the first request and a mean of 2.1 (SD = 1.2) for subsequent requests. Administrative errors were the most common source of request for further information, occurring in all submissions. The second most common theme was the content of the Participant Information and Consent

Corresponding author:
Caitlin Brandenburg, Faculty of Health Sciences and Medicine, Bond University, 14 University Drive, Gold Coast, QLD 4229, Australia.
Email: cbranden@bond.edu.au

Form, occurring in 79% of submissions. Other common themes, present in over 50% of submissions, concerned: data collection and study procedures; general ethical considerations; recruitment and consent; site, setting or patient pool; research design and methodology; and data management and security. In terms of the general purpose of the HREC comments, 44% were direct corrections or specific requests for changes, 42% were asking for more information or clarification of existing information, and 14% were the HREC expressing concerns about an element of the study, without directly suggesting a change. Overall, the study provides some evidence to show that the quality of the submission (ensuring correct attachments, up to date documents, clear information etc.) could account for a significant proportion of the burden and delay associated with ethical review.

Keywords
Audit, health services research, research ethics, ethics committees, ethical review process

In many countries, ethical review of human research is mandatory. In Australia, all human research conducted within public health institutions requires ethical review by a certified Human Research Ethics Committee (HREC), known in some countries as an Institutional Review Board (IRB). The primary purpose of ethical review is to ensure the protection of research participants.

Despite this important function, the process of ethical review has attracted significant criticism from the scientific community. Some have argued that mandatory ethical review, resulting in a binary outcome of approval or non-approval, can drive maladaptive attitudes in researchers. Colnerud (2015) contends that it turns the focus away from considered dialogue about ethical issues, towards getting a 'rubber stamp' of approval. The ethics review process is often perceived as 'red tape' by researchers, or even worse, a barrier to conducting research, rather than an important process for protecting research participants (Burris and Welsh, 2007; Guta et al., 2013). Key criticisms of the process include role creep (Angell et al., 2008; Guta et al., 2013), an increasing regulatory approach (Guta et al., 2013), perceived lack of competence with some research approaches (Colnerud, 2015; Guta et al., 2013), variability between HRECs with the same submission (Coleman and Bouesseau, 2008; Colnerud, 2015; Glasziou and Chalmers, 2004), unnecessary review of scientific merit (Angell et al., 2008; Page and Nyeboer, 2017) and lack of transparency of decision making (Klitzman et al., 2020; Glasziou and Chalmers, 2004; Guta et al., 2013; Lynch, 2018).

However, the key criticism of HRECs is the time for approval and the resource use associated with lengthy approval periods (Barnett et al., 2016; Guta et al., 2013; Maskell et al., 2003). Some commentators have debated the controversial possibility that mandatory ethical review is killing patients because of delays to important interventional research (Christie et al., 2007; Hunter, 2015; Whitney and Schneider, 2011), the assumption being that the time and resources for

ethical review process don't always advance the primary function of protecting participants.

One of the key sources of delays and demands upon resources is that it is uncommon for a decision to be reached upon first review[1] (Cleaton-Jones, 2016; Happo et al., 2017). Most submissions will be required to answer at least one request for further information or provide clarification for the HREC. The researchers then need time to develop a response to the request, which then needs to be reviewed again by the HREC, which can add months to study timelines (Page and Nyeboer, 2017). This is a major factor in lengthy review timelines and extra resource use, meaning that requests for further information are undesirable for both parties.

Quantifying the common reasons that ethics applications are returned to researchers could be useful for understanding reasons why delays are occurring and helping to minimise them. Despite the many criticisms of the HREC review process, few studies have investigated the functioning and evaluation of HRECs in an empirical manner, especially across multiple submissions (Nicholls et al., 2015; Sherzinger and Bobbert, 2017). A significant portion of the literature on this topic takes the form of researcher commentary or case studies that describe review of a single submission/project. This may be, in part, because HRECs can be reluctant to participate in research which evaluates their activities (Klitzman et al., 2020).

Several studies have investigated common reasons for request of further information from multiple submissions to HRECs across a range of countries (see, for instance: Bueno et al., 2009; Butler et al., 2020; Cleaton-Jones, 2016; Martín-Arribas et al., 2012; van Lent et al., 2014), but none have been undertaken in the Australian public health setting. In addition, many of these studies analysed comments to a low degree of specificity, often using only 4–10 broad categories like 'informed consent' or 'study sample'.

This study aimed to complete a detailed audit of the reasons for requests for further information across multiple submissions in a single Australian public health HREC. The study aimed to gain an understanding of the common issues, in order to help researchers and HRECs to understand if and how these requests can be minimised, for example through tailored education. It also aimed to provide information on the foci of HREC review, contributing to a better understanding of the role of HRECs in their core mission of protecting the rights of participants.

Methods

Requests for further information letters from an Australian public health service HREC in 2019 were investigated through retrospective audit. This particular

HREC reviews most research ethics applications for the health service district, which covers 600,000 residents and includes two major hospitals (790 and 400 beds). Some multisite research occurring in the district may have been reviewed by another HREC through Australia's national mutual acceptance scheme (New South Wales Health, 2020), and thus would not be included in the study.

Upon first review of an application, the HREC can either approve, reject or send a request for further information to the researcher. For requests for further information, this HREC separates each element of the request into dot points.

Content analysis was used to code each element of the request (usually each dot point) inductively into categories related to the content of the request. Each element was also coded deductively into the following three predefined categories relating to the purpose of the request:

- '*More information or clarification*' was used where the HREC's comment was related to the fact information was not present, or the information that was provided was not clearly understood by the HREC.
- '*Concern*' was used where, unlike the above category, the information was present and understood by the HREC, but there was a concern about an aspect of the study. The expected outcome of these queries was usually a justification or change of approach.
- '*Correction or request*' was also related to instances where there was concern with present and understood information, but the committee directly required or requested a specific change.

Initial coding was completed in Microsoft Excel by two authors (CB and ST), and all codes were reviewed by all three authors in regular coding review meetings. Coding finalisation was completed by one author (CB) and a subset was checked by the other two authors. Coders were either research ethics professionals, or researchers, with a minimum of 5 years of experience. After coding was completed, codes were summarised quantitatively.

Quantitative information was also collected on number of reviews, and number of elements per request for further information.

Results

It was originally intended that 12 months of data was to be analysed (approx. 100 submissions), however, withdrawal of management support for the project meant that only 24 consecutive submissions could be analysed. However, this data was rich enough to complete analysis, acknowledging that small sample size may limit interpretability. There was minimal crossover in investigator teams in the sample.

Out of a total of 117 investigators, one was Principal Investigator on two projects, and three were Associate Investigators on two or three projects.

Of these 24 submissions, all had requests for further information after initial review. Eighty-three percent had only one request for further information from the HREC, while 17% had more than one request, which included administrative requests (one study had an email administrative request prior to HREC review, and three had further, mostly administrative requests after HREC review). There was a mean of 14.2 (SD = 5.5) elements per request for the first request for further information. Subsequent requests had substantially fewer elements, with a mean of 2.1 (SD = 1.2).

In total, there were 355 elements of requests across 24 projects. Table 1 shows the all broad themes and categories with three or more occurrences from the 24 submissions. Data for all categories can be requested from the authors.

Administrative errors were the most common source of request for further information, occurring in 100% of submissions and making up 23% of all request elements. The most frequent form of administrative error, which appeared in 63% of projects, was missing documents, most commonly missing recruitment materials (6) and data collection tools (6), followed by Participant Information and Consent Forms (PICF: 4), and CVs (3). The second most common administrative error, occurring in over 50% of projects, was typographical or grammatical errors in participant-facing documents like recruitment materials and the PICF. The next most frequent error was a missing or incorrect footer. Other common errors related to inconsistent information between different documents, and incorrect/missing HREC details on the PICF.

The second most common theme was the content of the PICF, occurring in 79% of submissions and comprising 18% of all elements. The most common issues were that the wording of the PICF was unclear or too technical, there was an incomplete list of collaborators or institutions, or limited detail on study purpose and context.

Other common themes, present in over 50% of submissions, concerned: data collection and study procedures; general ethical considerations; recruitment and consent; site, setting or patient pool; research design and methodology; and data management and security.

In terms of the general purpose of the HREC comments, 44% were direct corrections or specific requests for changes, 42% were asking for more information or clarification of existing information, and 14% comprised HREC concerns about an element of the study, without directly suggesting a change. Notably, for comments related to administrative or PICF themes, the purpose was generally to make a correction or request a change (Figure 1).

Table 1. Themes and categories of requests for further information which occurred three or more times across the 24 submissions.

Theme	Category	*N* of occurrences	*N* (%) of submissions
Administrative: 100% of applications (*n* = 24), 23% of all categories (*n* = 80)	Missing documents (recruitment materials, data collection tool, PICF or CV)	21	15 (63)
	Typographical and grammatical errors on recruitment materials or PICF	15	13 (54)
	Missing or incorrect footers with document name, version and date	11	8 (33)
	Inconsistent information between different documents (HREA, protocol, PICF)	9	6 (25)
	Incorrect or missing contact details for HREC	8	5 (21)
	Layout of documents needs adjustment	5	5 (21)
	Missing clean or tracked change documents on resubmission	3	2 (8)
PICF: 79% of applications: (*n* = 19), 18% of all categories (*n* = 63)	Wording of PICF is not clear or too technical	7	4 (17)
	Incomplete list of collaborators and institutions	6	5 (21)
	Limited detail on study purpose and context	6	6 (25)
	Not enough information on data/sample storage	5	3 (13)
	Not enough information on risks/burdens to participants	5	5 (21)
	Not enough information on requirements of participants	3	3 (13)
	Not enough information on the identifiability of data	3	2 (8)
	Missing options or contact details for distressed participants	3	3 (13)
Data collection and study procedure: 75% of applications (*n* = 18), 11% of all categories (*n* = 40)	Not enough details on specifics of study procedures	12	8 (33)
	Not enough information on source of data and how it will be extracted	7	5 (21)
	Not enough information on validation of tool and any changes made to the tool	4	3 (13)
	HREC suggested change to questionnaire	3	3 (13)

(Continued)

Table 1. (Continued)

Theme	Category	*N* of occurrences	*N* (%) of submissions
General ethical considerations: 71% of applications (*n* = 17), 11% of all categories (*n* = 38)	Not enough information and justification of burden, risks and benefits	8	6 (25)
	Not enough information on funding, resources or in-kind support to conduct the study	5	3 (13)
	Not enough evidence of equipoise to justify RCT design	3	2 (8)
	Not enough information on provisions for clinical care of participants during/after the study	3	3 (13)
	Not enough detail on plan for disclosing health information and incidental findings to participants	3	2 (8)
Recruitment and consent: 63% of applications (*n* = 15), 9% of all categories (*n* = 33)	Not enough detail on how potential participants will be approached for recruitment	10	5 (21)
	More justification of exclusion criteria needed (especially regarding age and those who speak limited English)	6	5 (21)
	Inconsistent or unclear inclusion/exclusion criteria	4	3 (13)
	HREC identified that a waiver of consent was needed and requires justification	3	3 (13)
Site/setting/patient pool: 58% of applications (*n* = 14), 5% of all categories (*n* = 19)	Not enough information on number of potential participants and feasibility of recruitment	6	6 (25)
	Not enough information on target population – who they are and why they were chosen	6	4 (17)
	Not enough information on site and/or clinical setting	4	4 (17)
Research design and methodology: 58% of applications (*n* = 14), 6% of all categories (*n* = 20)	Not enough clarification of what is current standard practice	7	6 (25)
	Protocol does not have enough detail in general	3	3 (13)
	Not enough information on confounding variables and sources of bias	3	3 (13)

(Continued)

Table 1. (Continued)

Theme	Category	*N* of occurrences	*N* (%) of submissions
Data management/ confidentiality/security: 58% of applications (*n* = 14), 4% of all categories (*n* = 15)	Did not clarify identifiability of data (when and how it is deidentified, and who has access to identifiable data)	5	5 (21)
Data analysis and statistical considerations: 42% of applications (*n* = 10), 5% of all categories (*n* = 18)	Not enough information on sample size and how it was calculated	8	6 (25)
	Not enough information on statistical analysis	6	4 (17)
Investigators/collaborators/staff: 33% of applications (*n* = 8), 5% of all categories (*n* = 16)	Not enough information on investigator and personnel roles	9	7 (29)
	Not enough information on training of personnel	4	3 (13)
	Background/aims/hypotheses	6	
	After the study: impacts/future/dissemination	3	
	Other	4	
	Total	355	

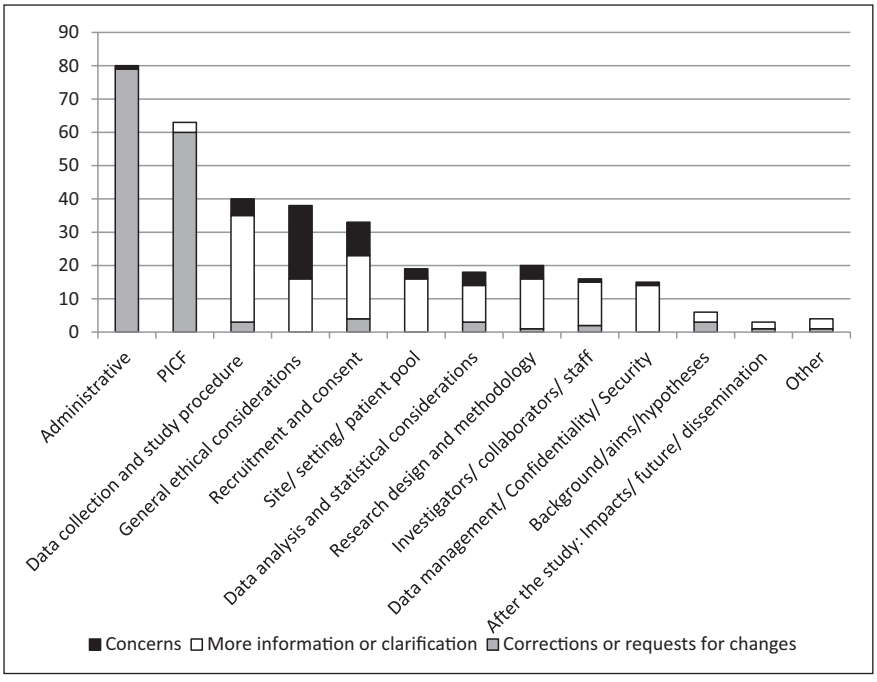

Figure 1. Frequency of general purpose of HREC comments, separated by broad theme.

Discussion

The mean number of reasons for return per letter (14.2) was significantly more than Bueno et al.'s (2009) mean of 2.2 per letter and Martín-Arribas et al.'s (2012) median of 4. The reasons for this large difference are unclear and may relate to differences in the nature of the submissions or ethical review standards and processes between sites. Importantly, this study did not investigate the value of the requests in protecting participants, so the usefulness of having a more detailed review is unknown (Angell and Dixon-Woods, 2009; Butler et al., 2020).

One of the main findings of this study was that administrative issues, such as missing documents or textual errors, were common. This finding is reflected in other studies (see, e.g. Angell and Dixon-Woods, 2009; Bueno et al., 2009; Butler et al., 2020; Cleaton-Jones, 2016; Davies, 2020; van Lent et al., 2014). As raised by Angell and Dixon-Woods (2009), it is unclear whether administrative corrections are helpful in advancing the core remit of HRECs to protect participants, or act as one of the contributors to researchers opining that HRECs are 'nit-picky' and focused on controlling elements of little importance (Burris and Welsh, 2007).

However, many of the administrative corrections noted in this study were related to missing documents, which is of obvious importance to thorough ethical review. This supports the idea that many elements of requests for further information from HRECs can be easily avoided when the researcher submits high quality, complete documentation in the first instance (Page and Nyeboer, 2017). In the (anecdotal) experience of the authors, researchers sometimes submit documents which are of lower quality in order to get their submission in the system as early as possible, with the expectation errors will be picked up upon review. In Australia, the national guiding document on ethical review is currently being revised to address this (NHMRC, 2020), with the sentence 'Researchers should be aware that the submission of poor quality proposals for review may delay the review, ethical approval and/or institutional authorisation process, with consequent impact on potential participants in the research or the community'. However, it should be noted that every submission in this study also had requests related to other categories, so absence of administrative errors would not have negated the need for the requests.

The next most common category related to issues with the PICF, a finding again reflected in many similar studies (Bueno et al., 2009; Butler et al., 2020; Cleaton-Jones, 2016; Martín-Arribas et al., 2012; van Lent et al., 2014). This is unsurprising, given the mandate of ethics committees to protect the rights of human participants, a key element of which is informed consent. Standardised PICF templates are useful in avoiding many issues although, in this case, these were already in use by this health service district. Other options to help minimise PICF-related issues may be specific education or guidance materials for developing PICFs, increasing awareness of the importance of the PICF, and a research culture which values health consumer engagement.

The purpose of most HREC requests was either for more information and clarification of existing information, or direct requests for changes. Cleaton-Jones (2016) also found that missing information, discrepancies and 'slip ups' (small errors requiring correction) accounted for a large volume of requests, with missing information an issue in almost 50% of submissions. These findings imply that submissions were submitted without enough information or were poorly written with unclear information, and that some requests for further information could be avoided with detailed, well-written protocols. However, a key complaint from researchers is that ethical review is a 'black box', and it is unclear what the HREC requires from them (Fitzgerald et al., 2006; Page and Nyeboer, 2017). Thus, both researchers and HRECs may have a role to play in avoiding requests related to insufficient information or lack of clarity. Our health service and others in Australia have found value in providing a protocol template alongside the national ethics form. However, as it is designed for all research, it only serves to ensure the basic protocol sections are included and could be more specific for different research designs.

Also of note, most of the direct requests for changes were related to administrative errors and changes to the PICF. The HREC rarely gave direct suggestions for changes on other matters like methodology, data collection and recruitment. On one hand, this appears to contradict the view held by many researchers that HRECs overstep their role in ethical review by requiring or requesting that changes be made to the scientific design of the study (Angell and Dixon-Woods, 2009; Angell et al., 2008). On the other hand, some researchers feel the responses from HRECs are vague and unhelpful, and would prefer direct advice on how to address the issues (Colnerud, 2015).

Limitations

An important limitation of this study is that it did not investigate the perceived or actual value of the requests in improving the quality of a study or ensuring the protection of participants. A similar study (Butler et al., 2020) also analysed the researchers' responses to the HREC and found that 72% of the researchers had made changes to their protocol based on the review. However, another study (Wynn et al., 2014) found that of those researchers who had been recommended significant modifications to their protocol, only 35% felt the changes were helpful to the quality of their research, 40% regarded the changes as neutral, and 25% as actually detrimental to the quality of their research. In terms of whether the changes would protect the welfare of the research participants, only 20% gave a positive response; 10% said the changes requested were detrimental to protecting the welfare of participants and 70% were neutral (Wynn et al., 2014). It appears that from

the researcher's perspective, the changes made as a result of requests for further information could have low value in improving either research quality or protection of participants. However, this needs to be investigated more thoroughly, and from more perspectives, including a health consumer perspective. The study was also limited in that it did not collect information on time to approval, which could have provided useful information on the impact of requests for further information on study timeframes.

It should be noted that the generalisation of these results is limited by the small sample size, and the fact that all applications were for a single, Australian HREC. In the sample of 25 submissions, there were a variety of research designs and research populations, but there was insufficient data to determine any trends related to these variables Future research in this area should endeavour to sample more submissions across multiple sites.

Conclusions

Overall, this study provides some evidence to show that the quality of the submission (ensuring correct attachments, up to date documents, clear information) could account for a significant proportion of the burden and delay associated with ethical review. Many of the issues raised were administrative or a result of unclear or not enough information, rather than principal ethical concerns. As requests for further information negatively impact review times and resource use, it is important to develop ways to minimise them and remain focused on elements which are directly related to the protection of participants.

Page and Nyeboer (2017) proposed that we need change and education at three levels: the HREC, the institution and the researcher. While the literature has placed a lot of focus on the first two, there has been less focus on how researchers might minimise issues related to the quality and completeness of the submission. Possible ways of improving this range from very simple, for example, checklists of administrative requirements, to more complex, like improved ethics training for researchers, or more specific guidance from HRECs or national ethics bodies (for instance, standard guidance on data management/storage for the institution).

The results of this project will be used to help locally, to guide the education of researchers. However, they may also be relevant more widely, through creation of coding frame for other HRECs who wish to conduct a similar audit, and a set of results for comparison. In broad terms, this study supported the notion that it is the responsibility of both researchers and HRECs (which are, after all, mostly made up of fellow researchers) to work together to improve the process and minimise requests for further information, for the benefit of both parties and society in general.

Funding

All articles in Research Ethics are published as open access. There are no submission charges and no Article Processing Charges as these are fully funded by institutions through Knowledge Unlatched, resulting in no direct charge to authors. For more information about Knowledge Unlatched please see here: http://www.knowledgeunlatched.org

ORCID iD


Caitlin Brandenburg https://orcid.org/0000-0002-6992-7790

Note

1. In Australia, researchers are commonly asked for further information before a decision is taken.

References

Angell EL, Bryman A, Ashcroft RE, et al. (2008) An analysis of decision letters by research ethics committees: The ethics/scientific quality boundary examined. *Quality and Safety in Healthcare* 17: 131–136.

Angell EL and Dixon-Woods M (2009) Do research ethics committees identify process errors in applications for ethical approval? *Journal of Medical Ethics* 35(2): 130–132.

Barnett A, Campbell M, Shield C, et al. (2016) The high costs of getting ethical and site-specific approvals for multi-centre research. *Research Integrity and Peer Review* 1(16).

Bueno M, Brevidelli MM, Cocarelli T, et al. (2009) Reasons for resubmission of research projects to the research ethics committee of a university hospital in São Paulo, Brazil. *Clinical Science* 64(9): 831–836.

Burris S and Welsh J (2007) Regulatory paradox in the protection of human research subjects: A review of OHRP enforcement letters. *Northwestern University Law Review* 101(2): 643–685.

Butler AE, Vincent K and Bluebond-Langner M (2020) Insights into the perception that research ethics committees are a barrier to research with seriously ill children: A study of committee minutes and correspondence with researchers studying seriously ill children. *Palliative Medicine* 34(3): 413–423.

Christie DRH, Gabriel GS and Dear K. (2007) Adverse effects of a multicentre system for ethics approval on the progress of a prospective multicentre trial of cancer treatment: How many patients die waiting? *Internal Medicine Journal* 37: 680–686.

Cleaton-Jones P (2016) What changes are there in decisions by the Wits Human Research Ethics Committee (Medical) and in process errors by research applicants between 2003 and 2015? *South African Journal of Bioethics and Law* 9(2): 69–72.

Coleman CH and Bouësseau M (2008) How do we know that research ethics committees are really working? The neglected role of outcomes assessment in research ethics review. *BMC Medical Ethics* 9(6).

Colnerud G (2015) Ethical dilemmas in research in relation to ethical review: An empirical study. *Research Ethics* 10(4): 238–253.

Davies SEH (2020) The introduction of research ethics review procedures at a university in South Africa: Review outcomes of a social science research ethics committee. *Research Ethics* 16(1–2): 1–26.

Fitzgerald MH, Phillips PA and Yule E (2006) The research ethics review process and ethics review narratives. *Ethics and Behavior* 16(4): 377–395.

Glasziou P and Chalmers I (2004) Ethics review roulette: What can we learn? *BMJ* 328: 121–122.

Guta A, Nixon SA and Wilson MG (2013) Resisting the seduction of "ethics creep": Using Foucault to surface complexity and contradiction in research ethics review. *Social Science and Medicine* 98: 301–310.

Happo SM, Halkoaho A, Lehto SM, et al. (2017) The effect of study type on research ethics committees' queries in medical studies. *Research Ethics* 13(3–4): 115–127.

Hunter D (2015) Is research ethics regulation really killing people? *Medical Journal of Australia* 202(6): 338–339.

Klitzman R, Appelbaum PS, Murray A, et al. (2020) When IRBs say no to participating in research about single IRBs. *Ethics and Human Research* 42(1): 36–40.

Lynch HL (2018) Opening closed doors: Promoting IRB transparency. *The Journal of Law, Medicine and Ethics* 46(2018): 145–158.

Martín-Arribas MC, Rodríguez-Lozano I and Arias-Díaz J (2012) Ethical review of research protocols: Experience of a Research Ethics Committee. *Revista Española De Cardiología* 65(6): 525–529.

Maskell NA, Joes EL, Davies RJ, et al. (2003) Variations in experience in obtaining ethical approval for participation in a multi-centre study. *QJM* 96: 305–307.

New South Wales Health (2020). National mutual acceptance. Available at https://www.medicalresearch.nsw.gov.au/national-mutual-acceptance/ (accessed 13 February 2021).

NHMRC (2020) NHMRC public consultation: National Statement for Ethical Conduct in Human Research Sections 4 and 5. Available at: https://online.nhmrc.gov.au/public-consultation/national-statement-ethical-conduct-human-research-sections-4-and-5 (accessed 13 December 2020).

Nicholls SG, Hayes TP, Brehaut JC, et al. (2015) A scoping review of empirical research relating to quality and effectiveness of research ethics review. *PLoS One* 10: 0133639.

Page SA and Nyeboer J (2017) Improving the process of research ethics review. *Research Integrity and Peer Review* 2(14).

Scott AM, Kolstoe S, Ploem MC, et al. (2020) Exempting low-risk health and medical research from ethics reviews: comparing Australia, the United Kingdom, the United States and the Netherlands. *Health Research Policy and Systems* 18.

van Lent M, Rongen GA and Out HJ (2014) Shortcomings of protocols of drug trials in relation to sponsorship as identified by Research Ethics Committees: Analysis of comments raised during ethical review. *BMC Medical Ethics* 15: 83.

Whitney SN and Schneider CE (2011) Viewpoint: A method to estimate the cost in lives of ethics board review of biomedical research. *Journal of Internal Medicine* 269: 392–402.

Wynn LL, Israel M, Thomson C, et al. (2014) A national survey of experiences with ethics review. *The Australian Journal of Anthropology* 25(3): 375–377.